

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

)
LIFELINK PHARMACEUTICALS, INC.,) CASE NO. 5:07-cv-00785-JG
)
Plaintiff,)
) JUDGE JAMES S. GWIN
v.)
)
NDA CONSULTING, INC., *et al.*)
)
Defendants.)
)
)

**DEFENDANTS' JOINT POST-MARKMAN BRIEF IN SUPPORT OF CLAIM
CONSTRUCTION FOR U.S. PATENT No. 6,288,045**

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- Attachment N-3 Article (2004) - Ana Radosavljevic-Mihajlovic, et al., *Physicochemical and Structural Characteristics of HEU-Type Zeolitic Tuff Treated by Hydrochloric Acid*", J.SERB. CHEM.SOC., V. 69(4), pp. 273-281 (2004).
- Attachment N-4 Article (2004) - Fehime Cakicioglu-Ozkan. "*The Effect of HCl Treatment on Water Vapor Absorption Characteristics of Clinoptilolite Rich Natural Zeolite*", MICROPOROUS AND MESOPOROUS MATERIALS, Vol. 77, pp. 47-53 (2005).
- Attachment N-5 Article (1999) - Mark J. Rice, et al., "*Al next Nearest Neighbor R, Ring Occupation, and Proximity Statistics in ZSM-5*", JOURNAL OF CATALYSIS, Vol. 186, pp. 222-227 (1999).
- Attachment N-6 Article (1996) - C.R.A. Catlow, et al., "*Ab Initio and Molecular-Mechanics Studies of Aluminosilicate Fragments, and the Origin of Lowenstein's Rule*", Chem. Commun., pp. 1311-1312 (1996).
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I. INTRODUCTION

Pursuant to the Court's order of January 11, 2008 [Doc. 187], Defendants submit this Post-Markman Hearing Brief ("Brief"). As argued at the January 10, 2008 Hearing ("Hearing"), Defendants respectfully urge this Court to consider the following:

- (1) The claims as stated in the '045 Patent do not sufficiently inform one of *ordinary skill in the art* of zeolite chemistry what chemical entity the inventor has attempted to teach, in any meaningful or comprehensible way, thereby making it impossible to construe the claims of the '045 Patent in a way consistent with chemical reality; and
- (2) Alternatively, if any meaning at all is to be ascribed to the claims of the '045 Patent to enable one of *ordinary skill in the art* to understand the breadth and scope of the claims when construing the patent claims in light of the specification, it is essential at a minimum to look to Formula (I) - which is the particular molecular formula depicted by the inventor as being the invention of the '045 Patent. (See by reference Ex. A to Defs. Markman Brief in Support of Claim Construction ("Markman Brief" [Doc. 171], '045 Patent, col. 3, lines 47-60).)

This Post-Markman Brief is supported by the accompanying Exhibits, including the Supplemental Declaration of Dr. Edward Maginn, attached hereto and incorporated herein by reference (Exhibit N), together with the evidence previously admitted and referenced in Defendants' Markman Brief Supporting Claims Construction [Doc. 171]. This evidence, together with the Hearing testimony given by Defendants' expert, Dr. Maginn, as well as testimony from Plaintiff's expert Dr. Prabir Dutta, supports Defendants' positions regarding claim construction of the '045 Patent.

II. THE COURT SHOULD RULE THAT THE CLAIMS CANNOT BE CONSTRUED

A. *The Court Has Authority To Determine Patent Claims Cannot Be Construed.*

During the process of claim construction, patents usually “are to receive a liberal construction, and under the fair application of the rule, *ut res magis valent quam pereat*, are, if practicable, to be so interpreted as to uphold and not to destroy the right of the inventor.” *Turrill v. Mich. S & N Ind. R.R.*, 68 U.S. 419, 510 (1863). Considering this, emphasis must be given to the phrase “if practicable,” as in the instant case, construing the claims is not “practicable.”

As a general matter, a federal district court construing patent claim terms, clauses or phrases, may decline to construe a claim under principles of claim construction, where a “construction cannot be given.” *Phase Four Industries, Inc. v. Marathon Coach, Inc.*, Slip Copy, 2006 WL 3742216 (N.D.Cal., 2006). In *Marathon Coach*, the District Court for the Northern District of California determined it was appropriate practice for the Court “to **decline** to **construe** a word or phrase if it determines, pursuant to the principles of claim construction, that a construction cannot be given.” *Id.* at *2. (Slip Op. attached as Exhibit I) (emphasis added). The Court went on to direct that “[w]hen the declination to construe a word or phrase renders a claim arguably indefinite, the Court will identify that issue and leave it to the parties to bring a motion directed to that issue.” *Id.*

Following this logic, the instant case presents a patent (the ‘045 Patent) where claim construction is not practicable. As set forth in Defendants’ Markman Brief [Doc. 171], and as further argued at the Hearing, this Court should decline to construe the claims of the ‘045 Patent because any plausible construction would violate fundamental laws of science, specifically those involving chemical and molecular bonding. Defendants supplement their arguments here reiterating the ‘045 Patent inherent deficiencies relevant to chemical nomenclature and the

related empirical and structural formulas. Defendants also supplement here their alternative arguments and proposed claim construction should the Court choose to construe the claims. (See *infra*, Section III.)

B. The Claims Are Meaningless And Cannot Be Construed.

Defendants maintain their position that in order to be intellectually honest and to fall within scientific reality, the claims of the ‘045 Patent cannot be construed, as the chemical nomenclature, chemical or empirical formula and molecular or structural formula that are set forth in the patent are meaningless gibberish and materially inconsistent. As explained below, this led to the European Patent Office rejecting the patent application three times and finally substantially revising the scope of the Patent. Additionally, any reasonable interpretation of the claims would violate several scientific principles.

1. The European Patent Office, Reviewing and Examining the Same Claims, Found the Claims To Be Meaningless.

At the Hearing, Defendants provided independent support showing that the claims of the ‘045 Patent are meaningless: the prosecution history of the European counterpart to the ‘045 Patent.¹ Read together or apart, the three EPO office actions (Exs. J-L), and the final EPO Notice of Allowance (Ex. M), show that the patent claims included in the ‘045 Patent, when read in light to the patent specification, are meaningless and incorporate nonsensical and incomprehensible chemical nomenclature (names) as well as empirical and structural formulas. It is appropriate for this Court to consider statements made in a foreign counterpart in this instance. (See Defendants’ Markman Brief, Exhibit E, Manbeck Decl. at ¶ 15.)²

¹ Excerpts from the European Patent Office (“EPO”) prosecution history are attached and incorporated herein by reference as Exhibits J – M.

² In his Declaration, Harry Manbeck, former Commissioner of the United States Patent & Trademark Office, cited the following authority to support this Court’s consideration of the corresponding file history: *Tanabe Seiyaku Co., Ltd. v. U.S. Inter. Trade Com’n.*, 109 F.3d 726, 732 (Fed. Cir. 1997) (Ex. E-5); *Caterpillar Tractor Co. v. Berco*

In seeking patent protection in Europe on the ‘045 Patent as issued in the United States, Plaintiff initially submitted to the EPO the identical proposed patent claims (Claim 1-19). However, as evident from subsequent Office Actions, Plaintiff’s claims for its “Epithelial Cell Cancer Drug” patent were all rejected by the EPO. Before the eventual European patent was issued, Plaintiff was forced to delete all illogical chemical nomenclature as well as empirical and structural formulas, including Formula (I), in spite of the fact that inventors can be their own lexicographer in Europe, just as they can in the United States.

(a) **EPO Office Action – October 27, 2003**

The first EPO Office Action dated October 27, 2003 rejected all 19 claims on the grounds that the claims were “obscure,” “inconsistent” and “doubtful.” In part, the examiner stated in his request for clarification:

The subject-matter for which protection is sought is not clear (Art. 84 EPC).

The various definitions of the compounds/compositions claimed (anti cancer drugs) as indicated at different places of the present application appear to be obscure and inconsistent, this making identification of the compounds doubtful (emphasis added):

*“4,5 di-cyclo, disilico, dimagnesium, dialumnino, oxyo (?), trihydrate
(3Mg⁺⁺.3Al₂O₃3SiO₂.3H₂O) which are in the acetate, sulfate, chlorate or brominate (?)
form”, see page 1, line 9/10,*

...

(Ex. J, EPO First Office Action) (emphasis appearing within Office Action).

These are the same claim terms, clauses or phrases Defendants argue are unclear and inconsistent, and as such, cannot be construed by one of ordinary skill in the art of zeolite chemistry. The parties’ respective experts agree that the nomenclature, empirical and structural

SpA, 714 F.3d 1110, 1116 (Fed. Cir. 1983) (Ex. E-6); *Gillette co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed. Cir. 2005) (Ex. E-7).

formulas are not conventional for this field of science. (Exhibit N, Maginn Suppl. Decl. at ¶ 13; Exhibit O, Hrg Trans., pp. 34, 46-51, 65-68).

(b) EPO Office Action – July 26, 2004

The EPO's second Office Action dated July 26, 2004 again rejected all 19 claims as unclear. In part, the examiner stated in his second request for specific clarification:

1. The subject-matter for which protection is sought is still unclear (Art. 84 EPC).

1.1 ...

If said technical information concerning the compounds composition and/or structure is reliable, then the compound(s) of the invention should be defined on the basis of that information. However, the definition should also be consistent throughout the application (Cf. guidelines C-III 4.3).

...

- 1.2 The subject-matter of present claim 1 ('method for preparing') does not meet the requirements of Art. 84 EPC (clarity, support).

Indeed, the technical information provided by claim 1 is so vague and indefinite that it is unclear for which compounds actually protection is sought. Moreover, it is considered that the technical disclosure presented in the description as originally filed (see pages 4/5 "Synthesis of MAS") does not support such a generalized definition as provided by present claim 1 (which serves as reference for "product-by-process" claim 9).

The objected terms are "**a zeolite comprising (!) a sodium aluminosilicate,**" "**an acid**" (any?) and "**poloxy (?) compound**" (a term which appears to be unknown or at least very unusual in the art). Moreover, no reaction conditions are given.

...

- 1.3 Formula I on page 5 of the description is not quite clear. How is the 'left' cage-like (organic or inorganic?) structural moiety to be understood? What about divalent M₁ and M₃ which are tetravalent silicon and trivalent aluminium[sic], respectively?

...

(Ex. K, EPO Second Office Action) (emphasis appearing within Office Action).

The EPO examiner went on to state:

2. Clarification of the subject-matter (in particular, the chemical nature of the 'anti-cancer drug') for which protection is sought is necessary, preferably, on the basis

of what has been disclosed in the present application in concrete terms (see page 4/5). Otherwise, the grant of a patent cannot be expected.

...

(Ex. K) (emphasis added).

Again, the examiner's comments emphasize Defendants' criticism and argument that the corresponding claim terms, clauses or phrases in the corresponding U.S. '045 Patent are not at all clear and unambiguous such that one of ordinary skill in the art of zeolite chemistry take any meaning from the claims.

(c) **EPO Office Action – May 4, 2005**

The third Office Action dated May 4, 2005 shows yet another rejection of Plaintiff's proposed claims. The EPO examiner went so far as to say that "there is no possibility to clarify the structural formula on the basis of the disclosures as originally filed"(which was Plaintiff's corresponding U.S. '045 Patent). In part, the examiner stated in his third request for clarification:

1. The subject-matter of newly filed **claim 1** is still unclear, contrary to the requirements of Art. 84 EPC.

There is not any definition or explanation of the chemical nature of the left-handed 'cage' or 'box'-like moiety of the given formula. What atoms may constitute said moiety? Moreover, the side chain comprising Si, Mg and Al and oxygen appears to be obscure having regard to the bonds and valences of said components (atoms) shown in the formula.

The term "zeolite-based" does not help either to clarify matters. What exactly means "zeolite-based" in the given context and which (any?) zeolites may form said basis? According to the preparation method according to claim 2 the acid treatment of the zeolites has to be carried out in the presence of "iron oxide (Fe_2O_3), calcium oxide or sodium oxide." Is there no incorporation of said metal oxides/metals into the zeolite treated?

2. It would appear that there is no possibility to clarify the structural formula on the basis of the disclosure as originally filed.

....

Technical information which is not understandable in the presented form (cf. the formula/‘structure’ or terms such as “*4,5 dicyclo, disilico, dimagnesium, dialumino, oxyo, trihydrate*”) should better be deleted from the application documents in order to avoid further confusion (Art. 84 EPC).

3. The applicant is requested to file new claims which take account of the above comments.

....

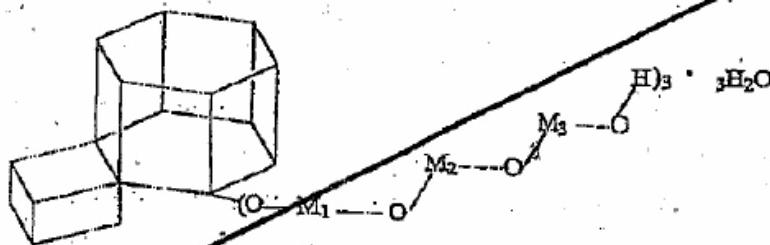
(Ex. L) (EPO Third Office Action) (emphasis added).

The examiner’s comments underscore that the corresponding claim terms, clauses or phrases as set forth in U.S. ‘045 Patent are not at all clear such to give meaning to the claims. This further suggests that the ‘045 Patent should not have issued in the first instance. (See also Defendants’ Markman Brief [Doc. 171], Ex. E, Manbeck Decl. at ¶¶ 7-14, 20.)

(d) EPO Notice of Allowance – October 20, 2005

In the Final Allowance, the EPO examiner took a pen to the application to make his point clear. Specifically, the examiner deleted (by hand) the inconsistent and vague chemical nomenclature and formulas appearing throughout the Background of the Invention, the Summary of the Invention, the Detailed Description of the Invention, and the claims themselves. The examiner crossed out the inappropriate references, including the title (“Epithelial Cell Cancer Drug”), the unclear chemical name (“*4,5 di-cyclo, disilico, dimagnesium, dialumnino, oxyo, trihydrate*”), the unclear empirical formula ($3Mg^{++}.3Al_2O_33SiO_2.3H_2O$), and the unclear structural formula (**Formula (I)**). (See Exhibit M, Notice of Allowance.)

15

~~The composition has a structure as follows:~~

Formula I

20

~~wherein M_1 is silicon, M_2 is magnesium, and M_3 is aluminum.~~

Defendants' expert, Commissioner Manbeck, states in his Declaration (Ex. E to Defendants' Markman Brief [Doc.171-10]) that the European patent history references clearly identify the '045 Patent's insufficiencies which should have been recognized during the application process at the USPTO for the '045 Patent. Commissioner Manbeck states in relevant part:

13. In my opinion, the reason why the United States examiner did not express the same concerns as the European examiner and Dr. Maginn may be due to the fact that in United States practice, the examiner is entitled to [[reply to]] rely upon the representations made in the patent application. That may well be what the United States examiner did. He presumably took as fact that the claims were definite in scope, defined actual compositions and that the claimed compositions could be produced by the disclosed method(s). Thus, the issuance of the patent would very likely have been based on the examiner's reliance on the inventor's representations which have been shown by Dr. Maginn to be incorrect and unsustainable.
14. In my opinion, the prosecution of the international counterpart of the '045 Patent is confirmatory of Dr. Maginn's conclusion which questions the ability of anyone skilled in the art to interpret the nomenclature found in the '045 Patent.

15. The consideration of statements made in prosecuting foreign counterparts is appropriate in some instances which do not involve purely procedural matters. . .

(Ex. E, Manbeck Decl. at ¶¶ 13-15) (emphasis added).

2. *The Claimed Invention Violates a Prime Tenet of Zeolitic Science: Lowenstein's Rule.*

Both experts and the inventor agree that Formula (I) is either derived from a zeolite or a zeolite fragment. Both Dr. Dutta and Dr. Maginn used conventional secondary building unit (SBU) notations – unique to zeolite science – when describing Formula (I) and independently referenced the Breck textbook of zeolites. Lowenstein's rule governs the structure of zeolites. It holds that two aluminum (Al) atoms must have at least two oxygen (O) atoms and a silicon (Si) atom in between.

Dr. Maginn's declarations and Hearing testimony support the chemical reality that the edge-to-edge bonding depicted in Formula (I) of the '045 Patent (col. 3, line 47-60) requires at least 5-coordinate bonding (meaning that the specific atom is bonded to five other atoms), a level of coordination only possible with aluminum. This inherently requires that two aluminum atoms be positioned at the vertices at each edge of the bond with a single oxygen atom in between -- thereby violating Lowenstein's rule. When faced with this chemical impossibility, Dr. Dutta testified that aluminum can have 5- and 6-coordination bonding under certain circumstances: more specifically, where the chemical reaction occurs in a strongly acidic environment, a pH of 3.0 or lower. What Dr. Dutta failed to state, but which Dr. Maginn explained is the fact that the invention product purportedly taught by the '045 Patent cannot be administered in a strongly acidic environment, but rather would be used in a neutral aqueous environment into a human at a

pH of between 7.0 – 7.4. (see Ex. O, Hrg. Trans. pp. 90-92; Ex. N, Maginn Suppl. Decl. at ¶¶ 4-12).

If Dr. Dutta wishes to use support for his assertion that aluminum can have 5- and 6-coordination under acidic conditions as shown in the paper by Swaddle et al. (Plaintiff's Markman Exhibit Q),³ then Dr. Dutta must also account for the rest of the statement in the paper that “the tetrahedral [four-bonded] aluminate ion … dominates at pH > 7”. As stated by Dr. Maginn, this means that aluminum returns to its 4-coordination chemistry under neutral or basic conditions. (See Ex. N, Maginn Suppl. Decl. at ¶ 12). Thus, when reviewed in its entire context, the Swaddle paper contradicts the proposition the 5- or 6-coordinate aluminum could exist at the vertices of Formula (I).

In short, Plaintiff neglected to give the complete story, and selectively referenced the Swaddle paper in a convenient but failed effort to overcome Lowenstein's Rule. Specifically, to administer the purported Formula (I) drug under conditions which would allow either direct injection or intravenous 24-hour drip into the bloodstream would render Formula (I) unstable. (Ex. N, Maginn Suppl. Decl. ¶ 12.) Alternatively, Plaintiff is advocating the injection of highly acidic solutions into the bloodstream, which Defendants' contend will yield potentially disastrous results. (Ex. N, Maginn Supp. Decl. at ¶ 12.) Therefore, a closer review of the articles Plaintiff admitted into evidence at the Hearing as Exhibits P and Q, shows that the articles actually contradict to the conclusions Plaintiff and Dr. Dutta suggested, thus further supporting Defendants' arguments.

³At the Hearing, Plaintiff admitted Ex. Q, a paper authored by Thomas W. Swaddle, et al., entitled “Kinetic Evidence for Five-Coordination in $\text{AlOH}_{(\text{aq})}^{2+}$ Ion,” SCIENCE, Vol. 308 (June 2005).

(a) **Mark J. Rice Article**

At the Markman Hearing, Plaintiff admitted into evidence an article by Mark J. Rice, et al., entitled: *Al next Nearest Neighbor R, Ring Occupation, and Proximity Statistics in ZSM-5, JOURNAL OF CATALYSIS*, Vol. 186, pp. 222-227 (1999) (Pltf.'s Exhibit P), for the proposition that the empirical and molecular/structural formulas set forth in the '045 Patent may be an exception to Lowenstein's Rule. However, Defendants' maintain this is not the case. In fact, contrary to the general proposition advanced by Dr. Dutta, this paper clearly states that Lowenstein's rule is correct, and that Al-O-Al linkages **are not energetically favorable.** (Ex. N, Maginn Suppl. Decl. at ¶ 10; Ex. O, 69-73).

Considering this framework, the Rice article does not support Plaintiff's proposition that there are "exceptions" in the present case that allow one of ordinary skill in the art to avoid the application of Lowenstein's Rule. Instead, it supports the proposition that Lowenstein's Rule must be satisfied. The declarations and Hearing testimony of Defendant's expert, Dr. Maginn, applying Lowenstein's Rule to the '045 Patent, accurately states that when applied to the molecular structure and empirical formula set forth in the '045 Patent, Lowenstein's Rule is not satisfied. (see Defs.' Ex. C to Defs.' Markman Brief [Doc. 171], Maginn Decl. at ¶17, 37(e). 39(a) and (b); see also Ex. N, Maginn Suppl. Decl. at ¶ 10; and Ex. O, Hrg. Trans. pp. 69-73).

(b) **The Catlow Paper**

Dr. Maginn has reviewed additional articles that support Defendants' position that despite Dr. Dutta's testimony, Lowenstein's rule still must be satisfied. In an article by C. R. Catlow, et al., entitled "*Ab initio* and Molecular-Mechanics Studies of Aluminosilicate Fragments, and the Origin of Lowenstein's Rule," CHEM. COMMUN. (1996) (Ex. N-6), the authors investigated the stability of small clusters and rings containing Si, Al and O atoms in solution and calculated

what arrangement of silicon (Si) and aluminum (Al) were stable. The article clearly indicates that one cannot form Al-O-Al linkages in small rings that are precursors to zeolites. Thus, they find that it is even more unlikely to violate Lowenstein's rule with small clusters (like Formula (I)) than to violate the same rule in an actual zeolite. (Ex. N, Maginn Suppl. Decl. at ¶ 11).

3. *There Is No Support In The '045 Patent Claims or Specification For Plaintiff's Presumed or Hypothesized Reaction Conditions.*

While it is possible to dealuminate (remove aluminum from) zeolitic starting material (such as sodium magnesium aluminosilicate) in the presence of strong acids, the acids used in the '045 Patent are simply not sufficiently strong to cause this reaction to occur.⁴ (Ex. O – Hrg./Trans. 77-78.) While the acids listed in the Patent are strong as they come out of the bottle, they are very significantly diluted (by more than one hundredfold), thereby making them "weak" as used in this context. Even assuming arguendo that appropriately strong acids were used, the literature shows that any extracted aluminum will form aquo complex ions (free aluminum bonded with water molecules) which may be 4-, or 5-, or 6-coordinate. The '045 Patent does not pertain to aquo complex ions of aluminum. Significantly, no research or writings from Dr. Dutta (or others for that matter) show that 5-coordinate or 6-coordinate aluminum aquo species incorporate themselves back into zeolite ring structures of the type shown in Formula (I). In fact, no literature exists showing that aluminum is ever found in anything other than a 4-coordination

⁴ The article by Radosavljevi-Mihajlovi (see Exhibit N-3, also Ex. N, Maginn Supp. Decl. at ¶ 6) teaches that using acid treatment at concentrations taught in the '045 Patent does not have any effect on the crystallinity of the treated zeolite. This means that the acid strength used in the '045 Patent is not strong enough to break the clinoptilolite lattice and contradicts the fanciful and self-serving claim that the acid strengths used in the '045 Patent can break apart portions of the starting zeolite lattice.

The article by Ozkan et al. (see Exhibit N-4, also Ex. N, Maginn Supp. Decl. at ¶ 7) shows that acid treatment of clinoptilolite does remove aluminum atoms, but once again, only at strong acid strengths. The weakest acid studied, which was stronger than that used in the '045 Patent, did essentially nothing to the starting zeolite, once again calling into question the applicability of the newfound enthusiasm by the Plaintiff of the acid theory.

state in a zeolite or a zeolite fragment. (Ex. N, Maginn Suppl. Decl. at ¶ 9.) Therefore, the testimony by Dr. Dutta regarding acidic environments and aluminum coordination is essentially irrelevant to the ‘045 Patent.

Additionally, it is unlikely that any reaction occurs in the synthetic methods described in the ‘045 Patent. As shown above, no aluminum will be removed. Just as clear, no silicon will be removed. (Ex. N, Maginn Suppl. Decl. at ¶ ----). This is significant, because if neither element is removed from the crystalline lattice of the starting material, then there is no source for either M_1 or M_3 in the trimetallic tail, further giving evidence that Formula (I) cannot be synthesized. The reaction process of the ‘045 Patent does not add any supplemental silicon or aluminum, and therefore the source for the elements in the trimetallic tail portion of Formula (I) must be the starting zeolite. However, there is no support in the literature that the conditions used in the ‘045 Patent are strong enough to accomplish this goal and in fact show exactly the opposite (i.e., nothing will happen other than ion exchange, which is not a chemical reaction involving the making or breaking of bonds, a definition proposed by the Plaintiff).

For these reasons, Defendants respectfully ask this Court to find that the claims of the ‘045 Patent cannot be construed.

III. IN THE ALTERNATIVE, DEFENDANTS SUGGEST THE FOLLOWING CONSTRUCTIONS.

In the alternative, Defendants respectfully suggest that the constructions on the following pages be adopted. In doing so, Defendants urge that if any meaning is to be given to these otherwise non-descript and illogical claims, then it should be at best, what is shown and proposed in the following charts, which further are summarized below.

A. Principles To Be Employer in Claim Construction.

Plaintiff tries to squeeze much mileage out of the quip: “Specifications teach. Claims claim.” However, Defendants’ contend the Plaintiff does so to avoid the logic and legally correct argument that the claims of the ‘045 Patent are limited to what is taught in Formula (I).

As a general matter, a court should look to the wording of the claims to “define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corporation*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Unfortunately, the claims in the current patent are indefinite and vague and the experts in the case to date have testified that standing alone, the claims of the ‘045 Patent are meaningless. More specifically, Defendants and their expert, Dr. Maginn argue the claims are co-extensive with what is taught by Formula (I). Plaintiff argues Defendants’ construction improperly imposes limitations from the specification into the claims.

Without a doubt, this Court may look to the specifications in order to construe the claims. See, e.g., *Markman v. Westview Instruments*, 52 F.3d 397, 979-980 (Fed. Cir. 1995) (“[c]laims must be read in view of specification, of which they are a part”). Indeed, “the best source for understanding a technical term is the specification from which it arose.” *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473 ,1478 (Fed. Cir. 1998).

Plaintiff’s argument that the claims cannot be limited by what is shown in Formula (I) is simply wrong. In numerous decisions, the Federal Circuit has found that the claims and specifications were limited to what was provided in the specification. See, e.g., *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337,1341-42 (Fed. Cir. 2001) (collecting and analyzing cases). The court has noted that usually the intent of the inventor is clear:

Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the

invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive. The manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent.

Phillips, 415 F.3d at 1323.

The intent of the inventor here is quite clear: Formula (I) is a molecular formula – essentially a picture – of a discrete molecule. It clearly shows a double four-sided ring attached to a double six-sided ring at an edge, with three tails coming off of the rings at different locations. It does not mention or acknowledge the existence of other members of a class.

The plain language of the Patent outside of Formula (I) also makes clear that the patented invention is single (and a 4,5 variant) discrete molecule. The “Detailed Description of the Invention” provides that “[t]he composition of the present invention is 4,5 di-cyclo disilico, dimagnesium, dialumino, oxyo, trihydrate . . . used in its acetate, sulfate, hydrochlorate, or bromate salt forms.” Column 2, lines 55-58 (emphasis added). Similarly, the specification provides that “[t]he composition has a **structure** as follows:” pointing to Formula (I).⁵

Additionally, expert testimony supports the position that Formula (I) is the sole embodiment of Claim 1. Defendants’ expert, Dr. Maginn, testified that nothing in the patent would lead one skilled in the art to understand that Formula (I), which is critical to a construction of the claims, simply is illustrative of a larger class of substances having common features. (Ex. Q, Hrg. Trans. p. 75.) This is consistent with Dr. Dutta’s deposition testimony that Claim 1, viewed through the prism of Formula (I), teaches the presence of two double rings, connected at the vertices, with three tails coming off of three different vertices (Exhibit P, Dutta Depo Trans. pp. 90-94, 136.)

⁵ The inventor, in deposition testimony, made clear that Formula (I) was intended to be the only embodiment of the claimed invention. (Ex. D to Defs’ Markman Brief [Doc. 171], Kaufman Depo. 136:3-7).

With this, Defendants respectfully urge the Court to adhere to the plain language of the ‘045 Patent and construe the claims to be co-extensive with Formula (I).

B. General Constructions.

Claims 1 – 4 are to be construed consistently, accommodating the listed acid anions of the salt nomenclature used, understanding that the chemical nomenclature, empirical formula, and structural formula references contain terms, phrases or clauses not conventional or known in the art of zeolite chemistry (or any other field of chemistry for that matter), and that adopting these violate terms, clauses or phrases violates accepted chemical naming and bonding rules without any good reason or rationale to do so, including Lowenstein’s Rule;

Claims 5 – 8 must be construed consistently, understanding that the chemical nomenclature, empirical formula, and structural formula references contain terms, phrases or clauses not conventional or known in the art of zeolite chemistry (or any other field of chemistry for that matter), and that adopting these violate terms, clauses or phrases violates accepted chemical naming and bonding rules without any good reason or rationale to do so, including Lowenstein’s Rule;

Claims 9 – 14 must be construed to give meaning to an end product that is the result of a chemical reaction, as that reaction is defined in the patent including beginning with a starting material, sodium magnesium aluminosilicate, and ending with a pharmaceutically accepted cancer drug. More specifically, the “reaction product” is a product derived from a chemical reaction starting with reactants and in only the making and/or breaking of bonds. The reactants in the ‘045 Patent are zeolites (sodium magnesium aluminosilicate) and an acid. As a result of the making and/or breaking of bonds, a zeolite fragment is formed which is defined in the patent

as a 4,5 and 6-sided network of cavities holding anions and cations specifically having the characteristics illustrated by Formula (I), namely

- (i) one molecule containing one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and an anion associated with the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic; or
- (ii) the other molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion derived from one of the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic.

Claims 15 – 19 must be construed to give meaning to the method of treating epithelial cell cancer by use of a substance effective in curing, mitigating, treating, or preventing cancer administered by injection directly into the tumor or a 24-hour intravenous slow drip, the substance being the product of discrete molecules derived from a zeolite (the molecules having one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion selected from the group of acetate, sulfate, chloirate, and brominates) sufficient to effectively treat such cancer, and such administration occurring by direct injection or 24-hour intravenous slow drip.

With this, Defendants' specific proposed constructions for these Claims are reiterated in the pages that follow.

C. Specific Constructions.

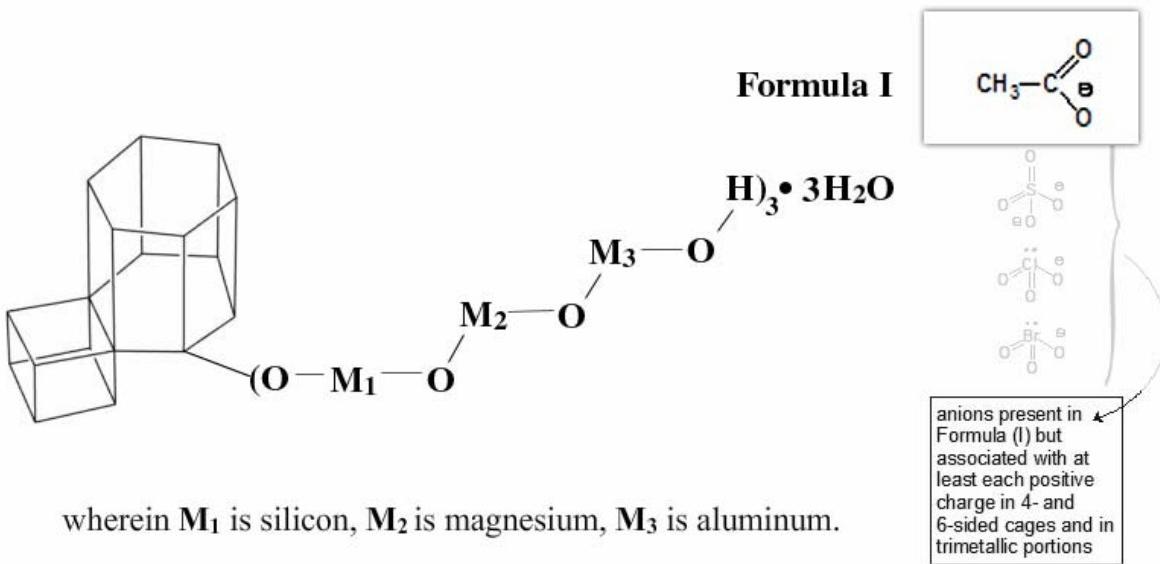
Claim 1. 4,6 cyclo, trisilico, trimagnesium, trialumino, oxyo, trihydrate acetate.

Word Description:

Preferred: A discrete molecule zeolitic fragment derived from a zeolite, the molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and an associated acetate anion.

Alternative: A discrete molecule derived from a zeolite, the molecule containing one double 4-membered ring and one double 6-membered ring bonded along either an edge, the faces, or a single point. The molecule further containing three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and an associated acetate anion.

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Chemical Description of Word Description:**Support for Preferred Construction:**

Both Plaintiff's and Defendants' experts agree that the words used in Claim 1 fail to teach one skilled in the art what is being claimed. (Ex. O, Hrg. Trans. pp. 38, 64-65.) Additionally, both experts agree that, to make any sense of the words used in Claim 1, one skilled in the art must look to Formula (I). (Ex. O, Hrg. Trans. pp. 38-39, 48-49, 68-69.)

Plaintiff argues that Formula (I) is simply an illustrative example of a "class of substances having similar features." But such an interpretation flies in the face of the plain language of the Patent, the inventor's intent, and what one skilled in the art would understand.

The plain language of the Patent makes clear that the patented invention is single, or two closely related, discrete molecule. The "Detailed Description of the Invention" provides that "[t]he composition of the present invention is 4,5 di-cyclo disilico, dimagnesium, dialumino, oxyo, trihydrate . . . used in its acetate, sulfate, hydrochlorate, or bromate salt forms." Column 2,

lines 55-58 (emphasis added). Similarly, the specification provides that “[t]he composition has a **structure** as follows:” pointing to Formula (I).

The inventor, in deposition testimony, made clear that Formula (I) was intended to be the only embodiment of the claimed invention. (Ex. D, Defs’ Markman Brief, Kaufman Depo. 136:3-7)

Finally, expert testimony supports the position that Formula (I) is the sole embodiment of Claim 1. Defendants’ expert, Dr. Maginn, testified that nothing in the patent would lead one skilled in the art to understand that Formula (I), which is critical to a construction of Claim 1, simply is illustrative of a larger class of substances having common features. (Ex. O, Hrg. Trans. pp. 75.) This is consistent with Dr. Dutta’s deposition testimony that Claim 1, viewed through the prism of Formula (I), teaches the presence of two double rings, connected at the vertices, with three tails coming off of three different vertices (Exhibit P, Dutta Depo Trans. pp. 90-94, 136.)

Additionally, Plaintiff’s expert, Dr. Dutta, clearly understood the invention named in Claim 1 to be a discrete molecule. (Ex. O, Hrg. Trans. pp. 44-45, 55, 60; Exhibit P, Dutta Depo Trans. pp. 52, 142.)

For additional support see previously submitted Defendant’s Markman Hearing Presentation Binder.

Support for Alternative Construction:

Both Plaintiff’s and Defendants’ experts agree that the words used in Claim 1 fail to teach one skilled in the art what is being claimed. (Ex. O, Hrg. Trans. pp. 38, 64-65.) Additionally, both experts agree that, to make any sense of the words used in Claim 1, one skilled in the art must look to Formula (I). (Ex. O, Hrg. Trans. pp. 38-39, 48-49, 68-69.)

Plaintiff's expert, Dr. Dutta, testified that Formula (I) taught him that Claims 1 through 6 teach two double rings with three tails attached to them – the tails containing oxygen, silicon, magnesium, and aluminum. (Ex. Q, Hrg. Trans. pp. 39, 50-51.) This is consistent with Dr. Dutta's previous deposition testimony that Claim 1, viewed through the prism of Formula I, teaches the presence of two double rings with three tails coming off of three different vertices. (Ex. P, Dutta Depo Trans. pp. 90-94, 136).

Additionally, Plaintiff's expert, Dr. Dutta, clearly understood the invention named in Claim 1 to be a discrete molecule. (Ex. Q, Hrg. Trans. pp. 44-45, 55, 60; Exhibit P, Dutta Depo Trans. pp. 52, 142.)

For additional support see previously submitted Defendant's Markman Hearing Presentation Binder.

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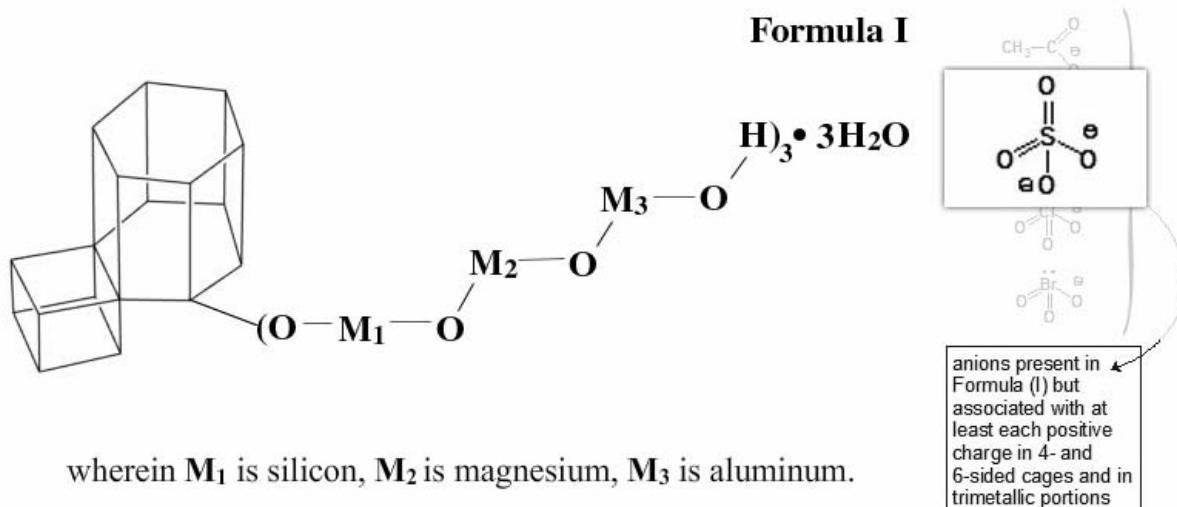
Claim 2. 4,6 cyclo, trisilico, trimagnesium, trialumino, oxyo, trihydrate sulfate.

Word Description:

Preferred: A discrete molecule zeolitic fragment derived from a zeolite, the molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and an associated sulfate anion.

Alternative: A discrete molecule derived from a zeolite, the molecule containing one double 4-membered ring and one double 6-membered ring bonded along either an edge, the faces, or a single point. The molecule further containing three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and an associated sulfate anion.

Chemical Description of Word Description:



Support for Constructions:

Plaintiff's expert Dr. Dutta testified that the only difference between claims 1 and 2 is the acid resulting in the claimed invention. (Ex. O, Hrg. Trans. p. 19.)

Additionally, see support for constructions of claim #1.

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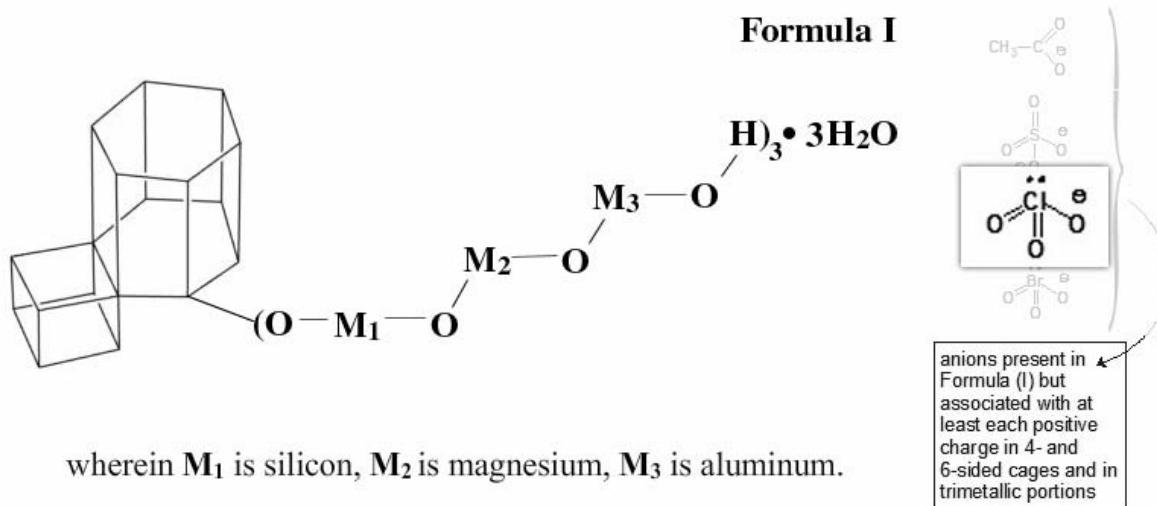
Claim 3. 4,6 cyclo, trisilico, trimagnesium, trialumino, oxyo, trihydrate hydrochlorate.

Word Description:

Preferred: A discrete molecule zeolitic fragment derived from a zeolite, the molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and an associated hydrochlorate anion.

Alternative: A discrete molecule derived from a zeolite, the molecule containing one double 4-membered ring and one double 6-membered ring bonded along either an edge, the faces, or a single point. The molecule further containing three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and an associated hydrochlorate anion.

Chemical Description of Word Description:



Support for Constructions:

Plaintiff's expert Dr. Dutta testified that the only difference between claims 1 and 3 is the acid resulting in the claimed invention. (Ex. Q, Hrg. Trans. pp. 19-20.)

Additionally, see support for constructions of claim #1.

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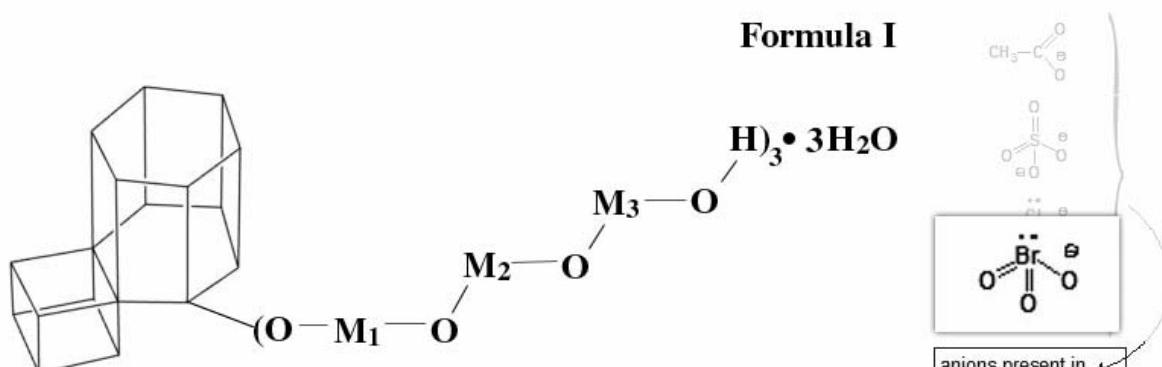
Claim 4. 4,6 cyclo, trisilico, trimagnesium, trialumino, oxyo, trihydrate brominate.

Word Description:

Preferred: A discrete molecule zeolitic fragment derived from a zeolite, the molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and an associated brominate anion.

Alternative: A discrete molecule derived from a zeolite, the molecule containing one double 4-membered ring and one double 6-membered ring bonded along either an edge, the faces, or a single point. The molecule further containing three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and an associated brominate anion.

Chemical Description of Word Description:



anions present in
Formula (I) but
associated with at
least each positive
charge in 4- and
6-sided cages and in
trimetallic portions

Support for Constructions:

Plaintiff's expert Dr. Dutta testified that the only difference between claims 1 and 4 is the acid resulting in the claimed invention. (Ex. Q, Hrg. Trans. p. 20.)

Additionally, see support for constructions of claim #1.

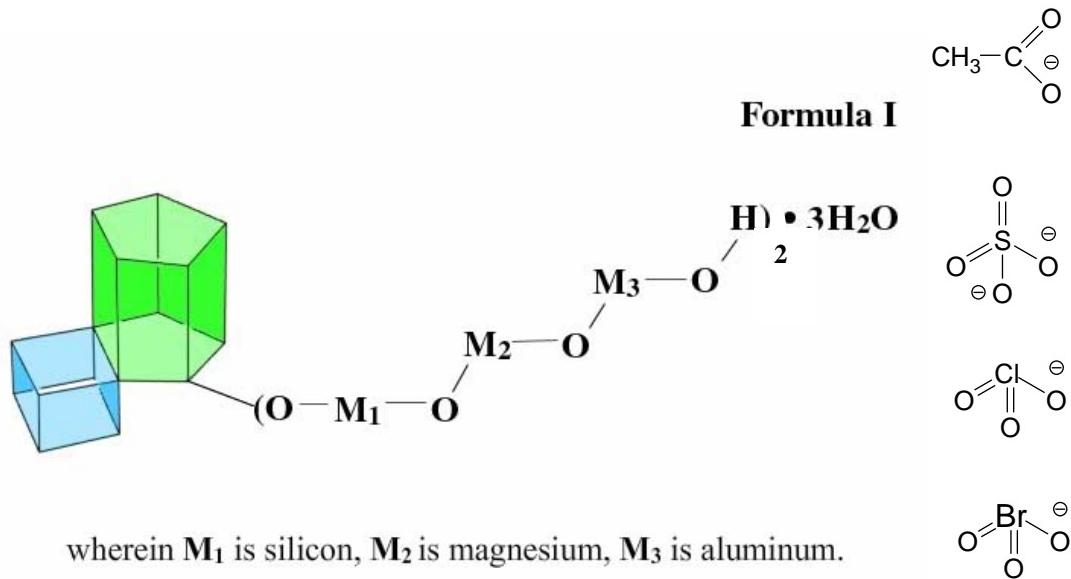
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Claim 5. A composition consisting essentially of 4,5 di-cyclo, disilico, dimagnesium, dialumino, oxyo, trihydrate acetate, sulfate, chlorate, or brominate.

Word Description:

A discrete molecule zeolitic fragment derived from a zeolite, the molecule containing one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and one of the following anions, namely, acetate, sulfate, chlorate or brominate.

Chemical Description of Word Description:



Support for Construction:

See support for construction of claim #5 contained in Defendants' Markman Brief Supporting Claim Construction for U.S. Patent No. 6,288,045.

Additionally, see support for constructions of claim #1.

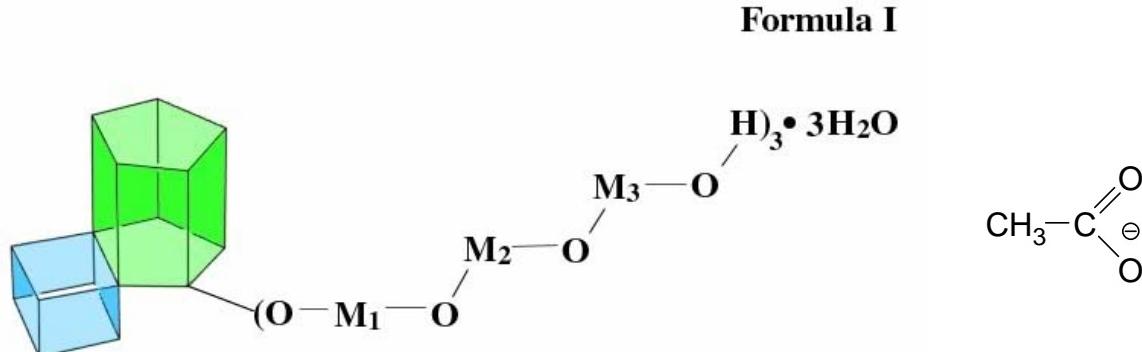
Claim 6. A pharmaceutical composition comprising a drug selected from the group consisting essentially of 4,5 cyclo, trisilico, trimagnesium, trialumino, oxyo, trihydrate acetate, 4,6 cyclo, trisilico, trimagnesium, trialumino, oxyo, trihydrate sulfate, 4,6 cyclo, trisilico, trimagnesium, trialumino, oxyo, trihydrate chlorate, and 4,6 cyclo, trisilico, trimagnesium, trialumino, oxyo trihydrate brominates, and a pharmaceutically acceptable carrier.

Word Description:

A substance or mixture sold or distributed by a pharmacist which treats a disease and comprised of one or more discrete molecules which are derived from a zeolite and administered by injection or 24-hour intravenous slow drip, the molecules having two different double ring structures:

(a) one molecule containing one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and an acetate anion;

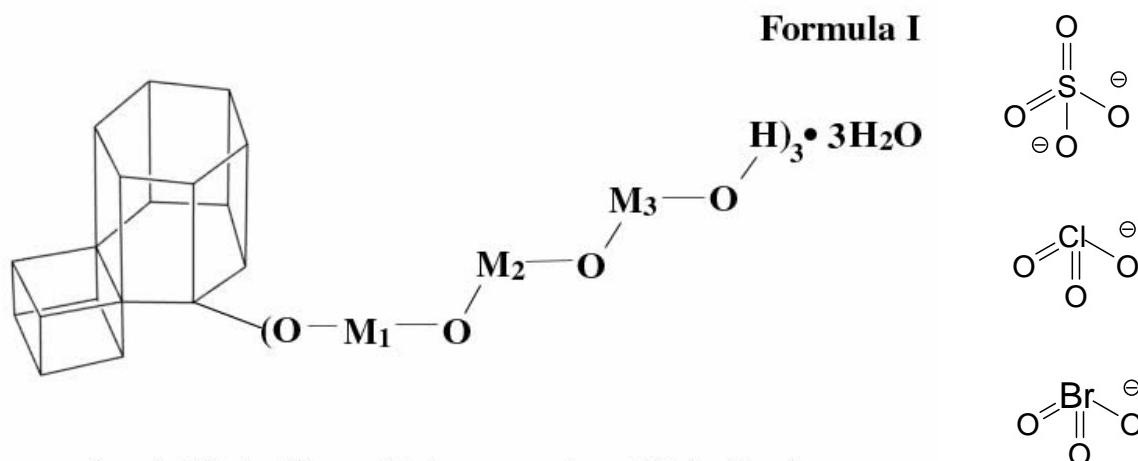
Chemical Description of Word Description of (a):



wherein \mathbf{M}_1 is silicon, \mathbf{M}_2 is magnesium, \mathbf{M}_3 is aluminum.

Word Description (con't):

(b) while the other molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing 3 trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and one of the following anions, namely, sulfate, chlorate or brominate.

Chemical Description of Word Description of (b):

wherein M_1 is silicon, M_2 is magnesium, M_3 is aluminum.

Support for Construction:

See support for construction of claim #6 contained in Defendants' Markman Brief Supporting Claim Construction for U.S. Patent No. 6,288,045.

Additionally, see support for constructions of claims 1 - 5.

Claim 7. The composition of claim 6 wherein said drug is present in an amount of between about 0.001 and about 1000 milligrams.

Word Description:

A substance or mixture sold or distributed by a pharmacist which treats a disease and is comprised of one or more discrete molecules which are derived from a zeolite and administered by injection or 24-hour intravenous slow drip, the molecules having two different double ring structures and administered in an amount between 0.001 and 1000 milligrams:

- (a) one molecule containing one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and an acetate anion;
- (b) the other molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing 3 trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and one of the following anions, namely, sulfate, chlorate or brominate.

Chemical Description of Word Description:

See above chemical structures for claim #6.

Support for Construction:

See support for construction of claim #6.

Claim 8. The composition of claim 6 wherein said drug is present in an amount of between about 20 and about 300 milligrams.

Word Description:

A substance or mixture sold or distributed by a pharmacist which treats a disease and is comprised of one or more discrete molecules which are derived from a zeolite and administered by injection or 24-hour intravenous slow drip, the molecules having two different double ring structures and administered in an amount between 0.001 and 1000 milligrams:

- (a) one molecule containing one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and an acetate anion;
- (b) the other molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing 3 trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and one of the following anions, namely, sulfate, chlorate or brominate.

Chemical Description of Word Description:

See above chemical structures for claim #6.

Support for Construction:

See support for construction of claim #6.

Claim 9. A cancer drug comprising the reaction product of a sodium magnesium aluminosilicate and an acid selected from the group consisting of glacial acetic, hydrochloric, sulfuric, hydro-bromic, and gluconic.

Word Description:

A substance effective in treating cancer administered by injection directly into the tumor or a 24-hour intravenous slow drip, the substance being the product of a chemical reaction involving the breaking or making of chemical bonds (or combinations thereof) the chemical reaction using the following two reactants:

- (a) a sodium magnesium aluminosilicate; and
- (b) an acid which is selected from one of the following, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic,

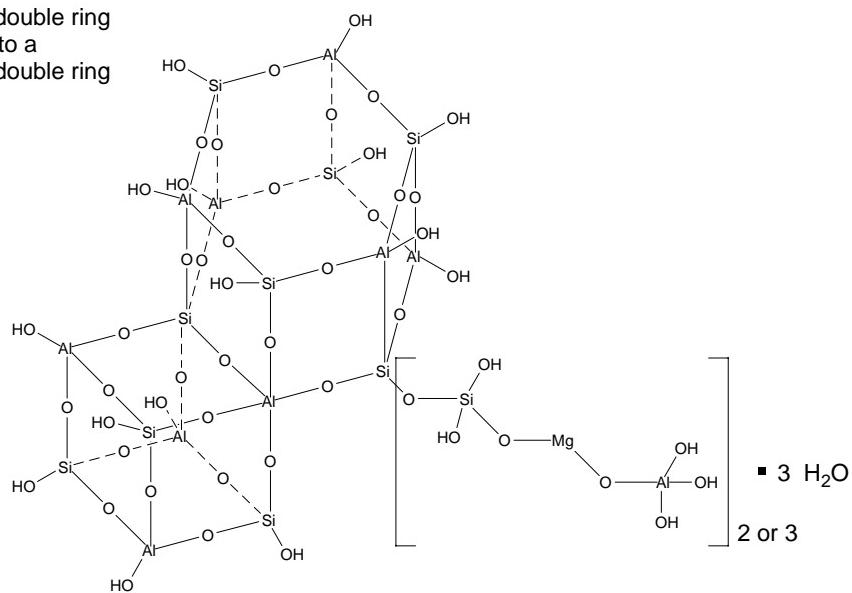
The resulting reaction product being a 4, 5, and 6-sided network of cavities holding anions and cations, specifically having the following characteristics illustrated by Formula (I):

- (i) one molecule containing one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and an anion associated with the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic; or
- (ii) the other molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion derived from one of the following acids, namely glacial acetic, hydrochloric, sulfuric,

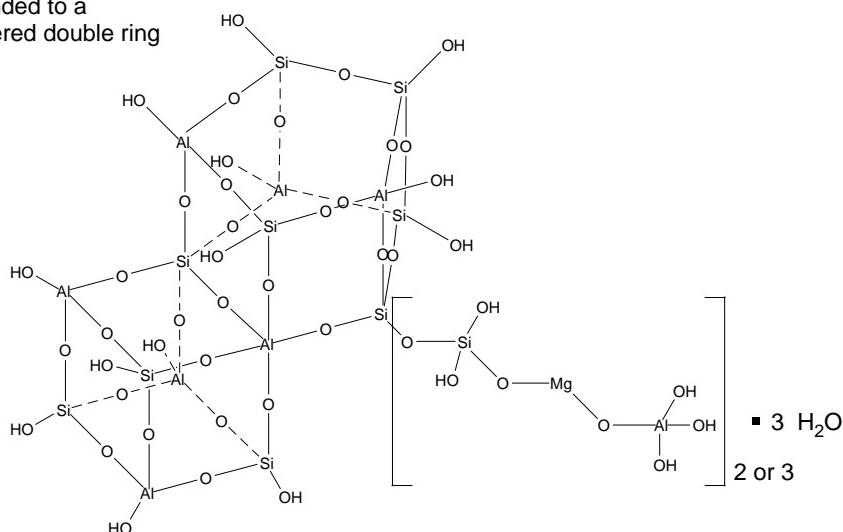
hydrobromic and gluconic.

Chemical Description of Word Description:

4-membered double ring
edge bonded to a
6-membered double ring



4-membered double ring
edge bonded to a
5-membered double ring



Support for Construction:

Both Parties' experts, Dr. Dutta and Dr. Maginn, testified that the term "reaction product," to one skilled in the art, means the result of the process in which chemical bonds are broken and new chemical bonds are formed. (Ex. O, Hrg. Trans. pp. 60-61, 84-85.)

Dr. Maginn also testified that, to one skilled in the art and reading the Patent as whole, claim #9 teaches the combination, under certain conditions, of sodium magnesium aluminosilicate and one of the listed acids. (Ex. O, Hrg. Trans. pp. 84-85.) He further testified that the Patent, read as a whole, indicates what the “reaction product” is: Formula I and its 4,5 variant. (Ex. O, Hrg. Trans. pp. 85-87.)

See support for construction of claim #9 contained in Defendants’ Markman Brief Supporting Claim Construction for U.S. Patent No. 6,288,045.

Additionally, see support for constructions of claims 1 - 5.

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Claim 10. The composition of claim 9 wherein the reaction is conducted in the presence of a polyoxy compound.

Word Description:

A substance effective in curing, mitigating, treating, or preventing cancer administered by injection directly into the tumor or a 24-hour intravenous slow drip, the substance being the product of a chemical reaction involving the breaking or making of chemical bonds (or combinations thereof) the chemical reaction using the following two reactants:

(a) a sodium magnesium aluminosilicate; and

(b) an acid which is selected from one of the following, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic;

(c) iron oxide, calcium oxide or sodium oxide;

The resulting reaction product being a 4, 5, and 6-sided network of cavities holding anions and cations, specifically having the following characteristics illustrated by Formula (I):

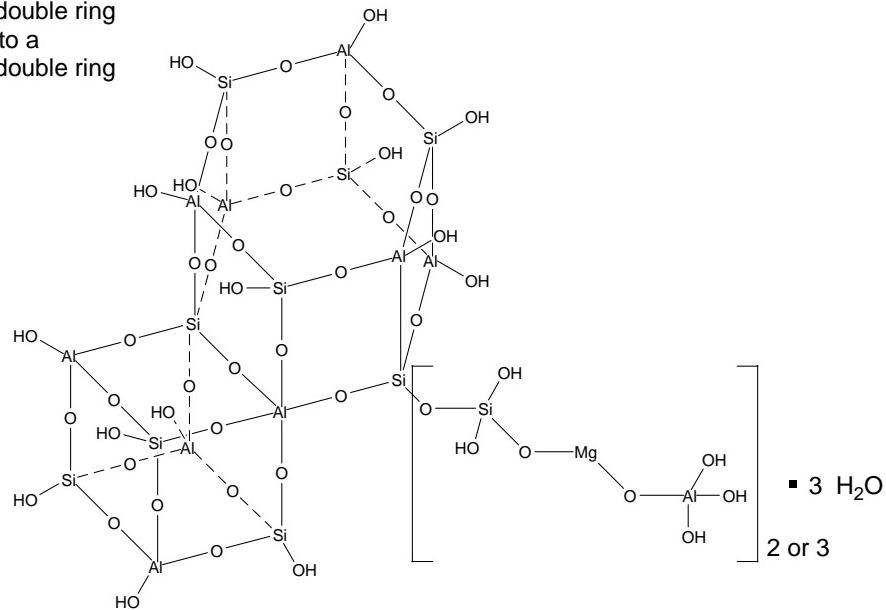
(i) one molecule containing one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and an anion associated with the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic; or

(ii) the other molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion

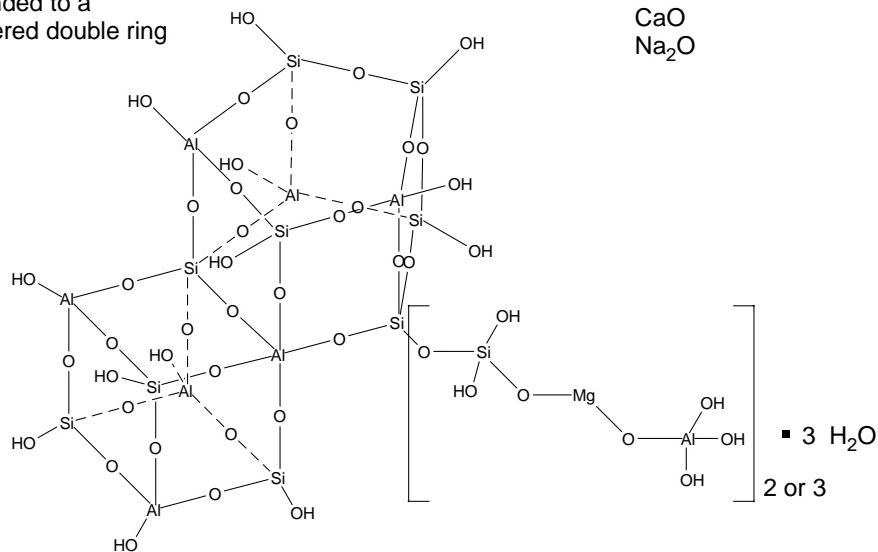
derived from one of the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic

Chemical Description of Word Description:

4-membered double ring
edge bonded to a
6-membered double ring



4-membered double ring
edge bonded to a
5-membered double ring



Support for Construction:

See same for claim #9 above, and support for claim #10 in Defs.' Markman Brief [Doc. 171].

Claim 11. The composition of claim 10 wherein the polyoxy compound is selected from the group consisting essentially of iron oxide, calcium oxide, and sodium oxide.

Word Description:

A substance effective in curing, mitigating, treating, or preventing cancer administered by injection directly into the tumor or a 24-hour intravenous slow drip, the substance being the product of a chemical reaction involving the breaking or making of chemical bonds (or combinations thereof) the chemical reaction using the following three reactants:

- (a) a sodium magnesium aluminosilicate; and
- (b) an acid which is selected from one of the following, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic;
- (c) iron oxide, calcium oxide or sodium oxide;

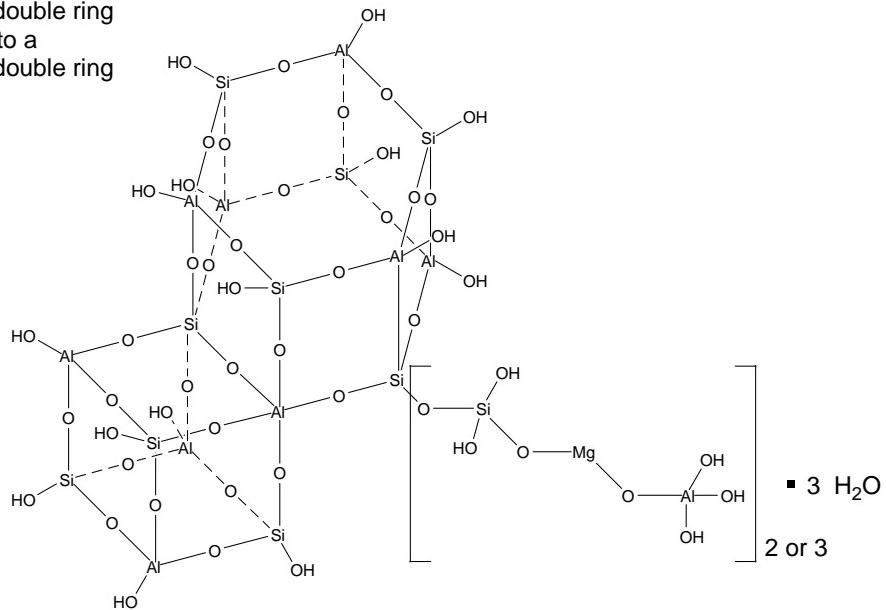
The resulting reaction product being a 4, 5, and 6-sided network of cavities holding anions and cations, specifically having the following characteristics illustrated by Formula (I):

- (i) one molecule containing one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and an anion associated with the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic; or
- (ii) the other molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion

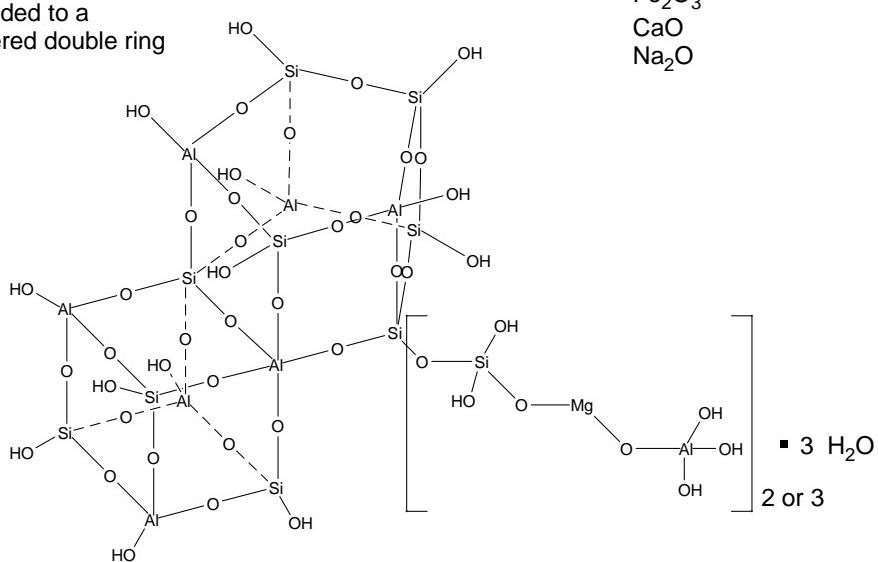
derived from one of the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic

Chemical Description of Word Description:

4-membered double ring
edge bonded to a
6-membered double ring



4-membered double ring
edge bonded to a
5-membered double ring



Support for Construction:

See same for claim #10 above, and support for claim #11 in Defs.' Markman Brief [Doc. 171].

Claim 12. The composition of claim 9 wherein the reaction is conducted at a temperature of between about 200 and 250°F.

Word Description:

A substance effective in curing, mitigating, treating, or preventing cancer administered by injection directly into the tumor or a 24-hour intravenous slow drip, the substance being the product of a chemical reaction between the temperatures of 200 and 250°F involving the breaking or making of chemical bonds (or combinations thereof) the chemical reaction using the following two reactants:

- (a) a sodium magnesium aluminosilicate; and
- (b) an acid which is selected from one of the following, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic,

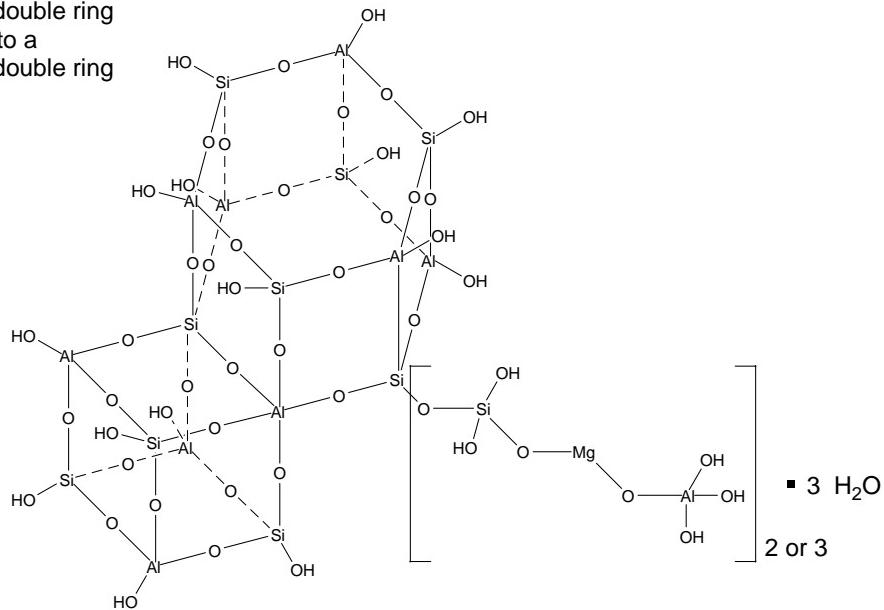
The resulting reaction product being a 4, 5, and 6-sided network of cavities holding anions and cations, specifically having the following characteristics illustrated by Formula (I):

- (i) one molecule containing one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and an anion associated with the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic; or
- (ii) the other molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion

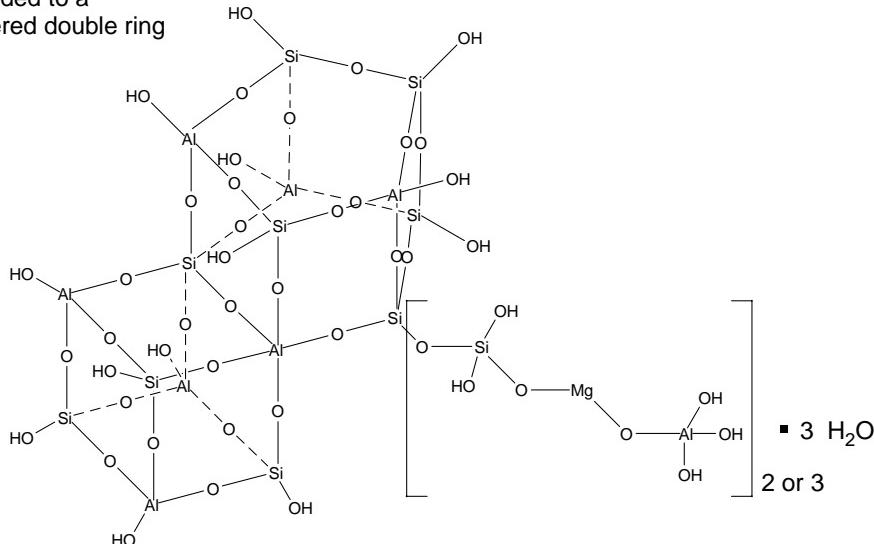
derived from one of the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic

Chemical Description of Word Description:

4-membered double ring
edge bonded to a
6-membered double ring



4-membered double ring
edge bonded to a
5-membered double ring



Support for Construction:

See same for claim #9 above, and support for claim #12 in Defs.' Markman Brief [Doc. 171].

Claim 13. The composition of claim 9 wherein the silicate is present in an amount of 20 to 40% by weight of the mixture and the acid is present in an amount of about 80 to about 60% by weight of the mixture of the silicate and the acid.

Word Description:

A substance effective in curing, mitigating, treating, or preventing cancer administered by injection directly into the tumor or a 24-hour intravenous slow drip, the substance being the product of a chemical reaction involving the breaking or making of chemical bonds (or combinations thereof) the chemical reaction using the following two reactants:

- (a) 20 to 40% by weight of a sodium magnesium aluminosilicate; and
- (b) 80 to 60% by weight of an acid which is selected from one of the following, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic,

The resulting reaction product being a 4, 5, and 6-sided network of cavities holding anions and cations, specifically having the following characteristics illustrated by Formula (I):

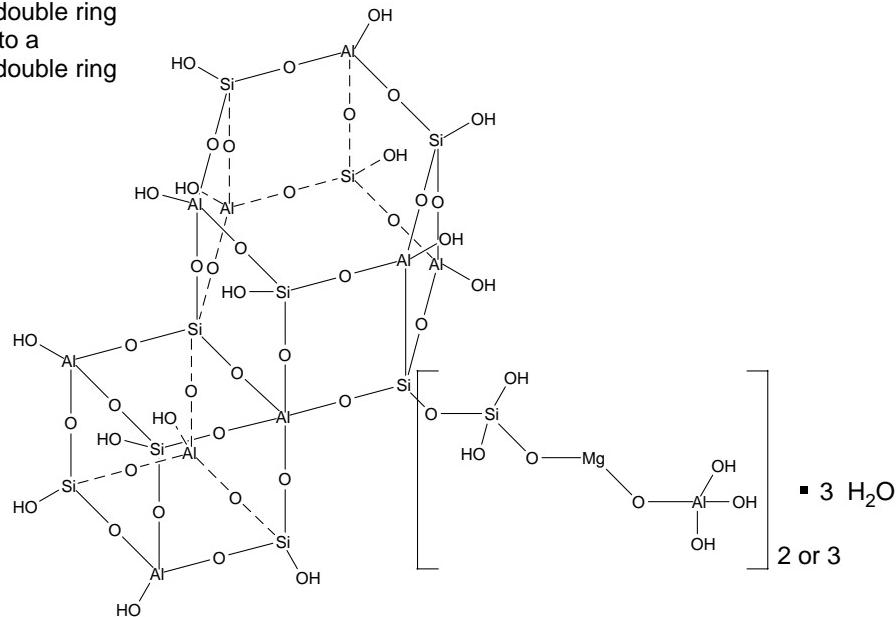
(i) one molecule containing one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and an anion associated with the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic; or

(ii) the other molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion

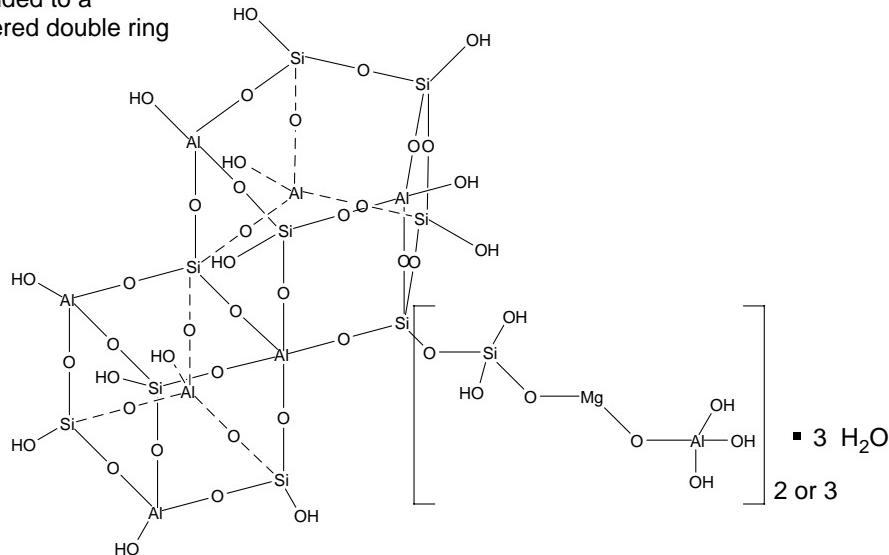
derived from one of the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic.

Chemical Description of Word Description:

4-membered double ring
edge bonded to a
6-membered double ring



4-membered double ring
edge bonded to a
5-membered double ring



Support for Construction:

See same for claim #9 above, and support for claim #13 in Defs.' Markman Brief [Doc. 171].

Claim 14. The composition of claim 10 wherein the polyoxy compound is present in an amount of between about 0.001 and 0.005% by weight.

Word Description:

A substance effective in curing, mitigating, treating, or preventing cancer administered by injection directly into the tumor or a 24-hour intravenous slow drip, the substance being the product of a chemical reaction involving the breaking or making of chemical bonds (or combinations thereof) the chemical reaction using the following three reactants:

- (a) a sodium magnesium aluminosilicate; and
- (b) an acid which is selected from one of the following, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic;
- (c) 0.001 to 0.005% by weight of iron oxide, calcium oxide or sodium oxide;

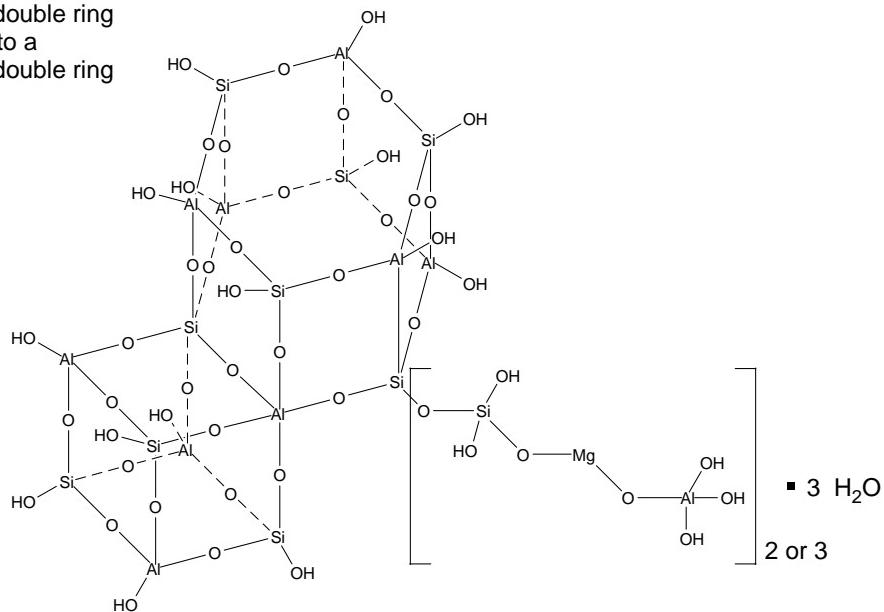
The resulting reaction product being a 4, 5, and 6-sided network of cavities holding anions and cations, specifically having the following characteristics illustrated by Formula (I):

- (i) one molecule containing one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules associated and an anion associated with the following acids, namely glacial acetic, hydrochloric, sulfuric, hydrobromic and gluconic; or
- (ii) the other molecule containing one double 4-membered ring and one double 6-membered ring bonded along an edge, the molecule further containing two or three trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion derived from one of the following acids, namely glacial acetic, hydrochloric, sulfuric,

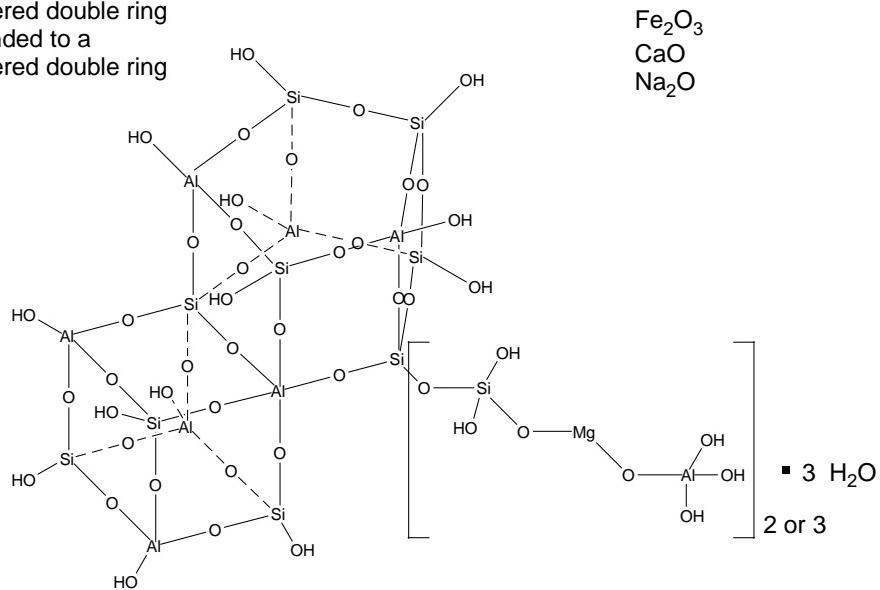
hydrobromic and gluconic.

Chemical Description of Word Description:

4-membered double ring
edge bonded to a
6-membered double ring



4-membered double ring
edge bonded to a
5-membered double ring



Support for Construction:

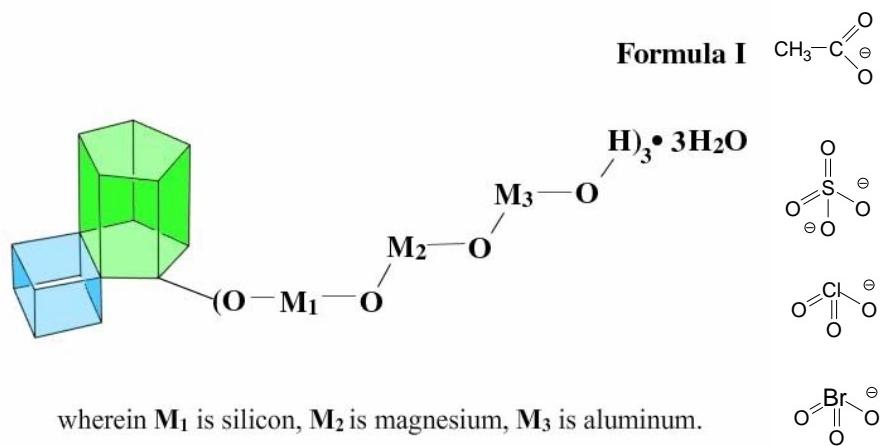
See same for claim #10 above, and support for claim #14 in Defs.' Markman Brief [Doc. 171].

Claim 15. A method of treating epithelial cell cancer comprising administering to a mammalian patient diagnosed as having an epithelial cell cancer a therapeutically effective amount of a drug selected from the group consisting of 4,5-dicyclo, disilico, dimagnesium, dialumino, oxyo, trihydrate acetate, sulfate, chlorate, and brominate.

Word Description:

A method of treating epithelial cell cancer by administration of an amount of discrete molecules derived from a zeolite (the molecules having one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion selected from the group of acetate, sulfate, chlorate, and brominates) sufficient to effectively treat cancer, and such administration occurring by direct injection or 24-hour intravenous slow drip.

Chemical Description of Word Description:



Support for Construction:

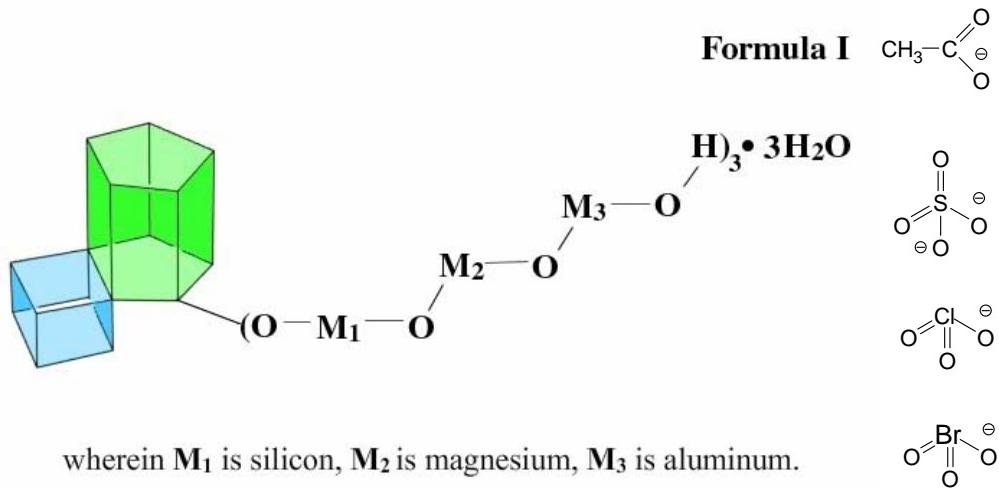
See same for claim #5 above, and support for claim #15 in Defs.’ Markman Brief [Doc. 171].

Claim 16. The method of claim 15 wherein the drug is dosed in about 0.001 to about 1000 milligrams.

Word Description:

A method of treating epithelial cell cancer by administration of an amount of discrete molecules derived from a zeolite (the molecules having one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion selected from the group of acetate, sulfate, chlorate, and bromates) sufficient to effectively treat such cancer, and such administration occurring via direct injection or 24-hour intravenous slow drip in an amount ranging from 0.001 to about 1000 milligrams.

Chemical Description of Word Description:



Support for Construction:

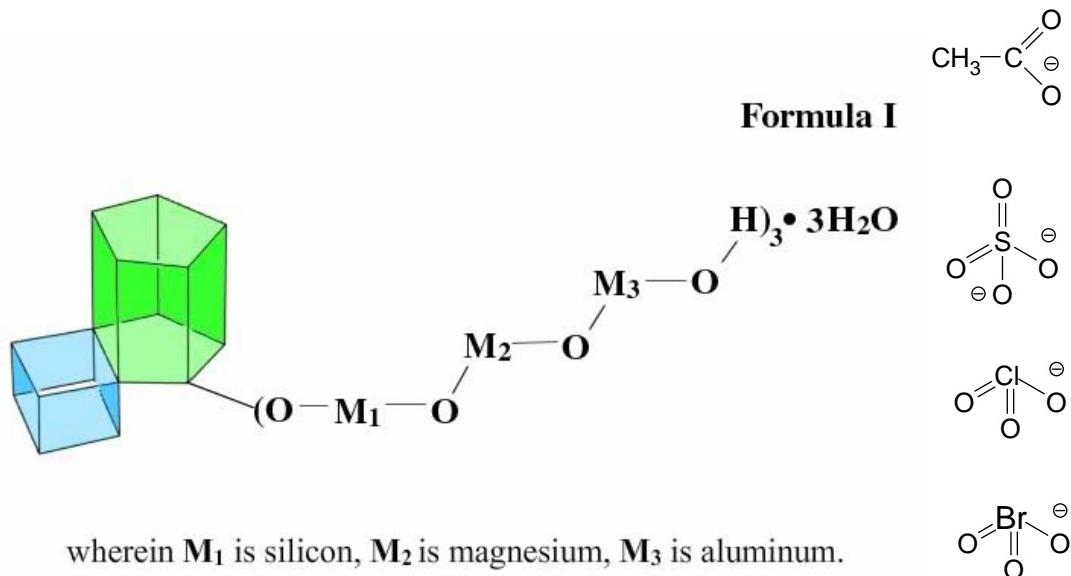
See same for claim #15 above, and support for claim #16 in Defs.' Markman Brief [Doc. 171].

Claim 17. The method of claim 15 wherein the drug is dosed in about 20 to about 300 milligrams.

Word Description:

A method of treating epithelial cell cancer by administration of an amount of discrete molecules derived from a zeolite (the molecules having one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion selected from the group of acetate, sulfate, chlorate, and brominates) sufficient to effectively treat such cancer, and such administration occurring via direct injection or 24-hour intravenous slow drip in an amount ranging from 20 to about 300 milligrams.

Chemical Description of Word Description:



Support for Construction:

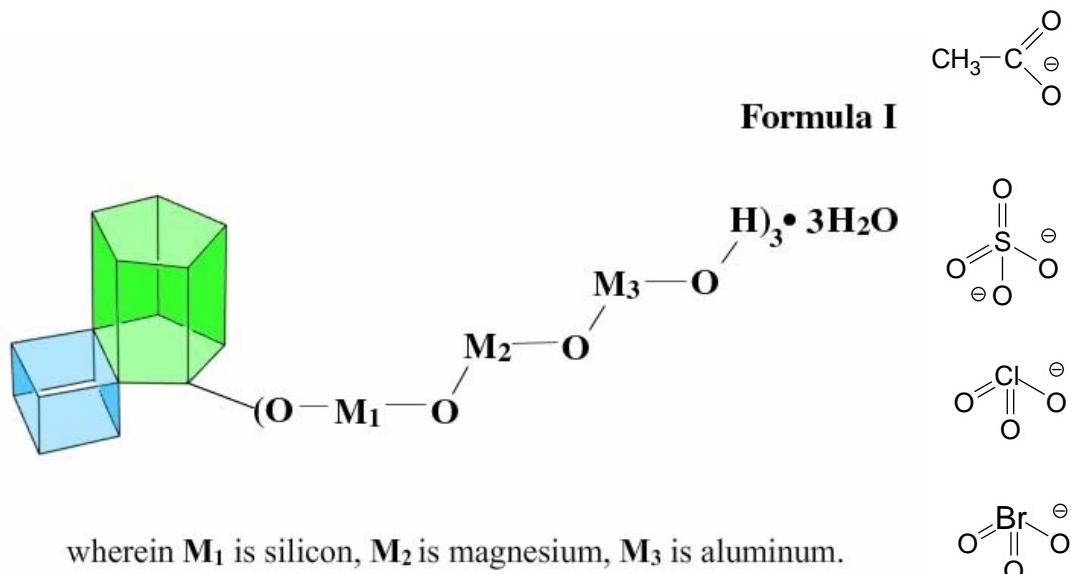
See same for claim #15 above, and support for claim #17 in Defs.' Markman Brief [Doc. 171].

Claim 18. The method of claim 15 wherein said compound is administered to a human..

Word Description:

A method of treating epithelial cell cancer in a human by administration of an amount of discrete molecules derived from a zeolite (the molecules having one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion selected from the group of acetate, sulfate, chlorate, and brominates) sufficient to effectively treat such cancer, and such administration occurring via direct injection or 24-hour intravenous slow drip.

Chemical Description of Word Description:



Support for Construction:

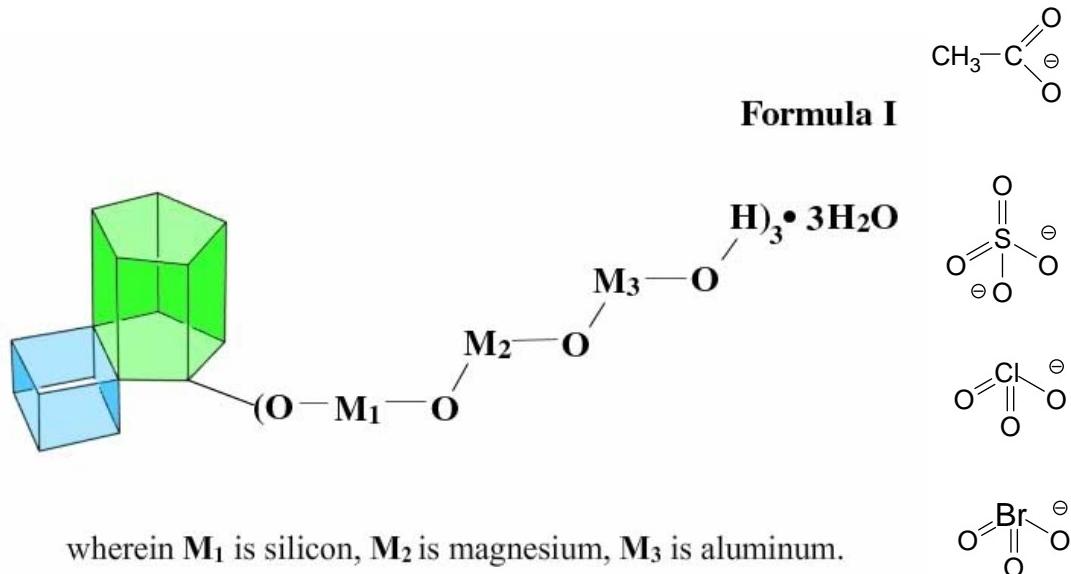
See same for claim #15 above, and support for claim #18 in Defs.' Markman Brief [Doc. 171].

Claim 19. The method of claim 15 wherein said compound is in combination with a pharmaceutically acceptable dilutent or carrier.

Word Description:

A method of treating epithelial cell cancer by administration of an amount of discrete molecules derived from a zeolite (the molecules having one double 4-membered ring and one double 5-membered ring bonded along an edge, the molecule further containing two trimetallic tails, each trimetallic tail containing sequentially oxygen – silicon – oxygen – magnesium – oxygen – aluminum – hydroxyl atoms, with three water molecules and one associated anion selected from the group of acetate, sulfate, chlorate, and brominates) in an aqueous solution sufficient to effectively treat such cancer, and such administration occurring via direct injection or 24-hour intravenous slow drip.

Chemical Description of Word Description:



Support for Construction:

See same for claim #15 above, and support for claim #19 in Defs.' Markman Brief [Doc. 171].

IV. CONCLUSION

For the reasons set forth above, Defendants respectfully request that this Court adopt its arguments regarding the construction of Claims 1 – 19 of the ‘045 Patent: in the first instance finding that the claims as stated in the ‘045 Patent do not sufficiently inform one of *ordinary skill in the art* of zeolite chemistry what chemical entity the inventor has attempted to teach, in any meaningful or comprehensible way, thereby making it impossible to construe the claims of the ‘045 Patent in a way consistent with chemical reality; or alternatively, finding that if any meaning at all is to be ascribed to the claims of the ‘045 Patent, then adopting the Defendants’ proposed claim construction as stated herein.

Respectfully submitted,

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CERTIFICATE OF SERVICE

Copies of the foregoing were electronically filed pursuant to the Court's ECF process. Parties and/or counsel with access shall be notified by operation of the Electronic Court Filing system.

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